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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	PATWA-2	5150
21559	7590	04/11/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1643	
DATE MAILED: 04/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/469,606

Applicant(s)

VOLLMERS ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,42,43 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,42,43 and 45-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 07, 2005 has been entered.

2. Claims 1, 4, 42, 43 and 45-56 are pending.

Claim 51 has been amended.

Claims 1, 4, 42, 43 and 45-56 are examined on the merits.

Withdrawn Rejection

Claim Rejections - 35 USC § 102

3. The rejection of claims 43, 45-49 and 51-56 under 35 U.S.C. 102(b) as being anticipated by Karnauchow et al. (Journal of Virology 70(8): 5143-5152, August 1996) is withdrawn in light of Applicants' arguments.

New and Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 4, 42, 43 and 45-56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue "[t]he claimed invention does not read on a genus of glycoproteins with undefined glycostructures, but rather to a particular isolated glycoprotein with a particular glycostructure and sections of the glycoprotein having the particular glycostructure" and as described in the specification Applicants' meet the written description requirement, see Remarks submitted December 07, 2005, page 7. Applicants aver given a publicly deposited cell line expressing a glycoprotein having the glycostructure is described in the specification and meets the standard set fourth by the Federal Circuit in *Enzo Biochem*, see page 8 of the Remarks. Applicants conclude arguments noting, "CD55/DAF only contains one N-linked glycosylation site" and "...the sequence of the primary structure of CD55 and the location, in this sequence, of the single N-linked glycosylation site were known and publicly available at the time of filing, see pages 11 and 12 of Remarks. These points of view and arguments have been carefully considered but found unpersuasive.

While the Examiner concurs that there may be just one N-linked glycosylation

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site this information does not provide relevant identifying characteristics and details on the tumor-specific N-linked glycostructure listed in the claims. It remains unclear what the structure is of the tumor-specific N-linked glycostructure. The art attests to the fact, carbohydrate moieties are complex, see Knight (BioTechnology 7(1): 35-40, Jan 1989). And while Knight speaks of differences between alterations the "bottom line" is the structures of glycostructures are hard to characterize. Unlike linear amino acid alterations, which can be readily synthesized in vitro, carbohydrate moieties are more complex and difficult to synthesize. Knight likens this task to "wrestling with a cloud". She states that "prediction and control of the expression of oligosaccharide remains elusive and threatens to remain so from some time" and the challenge is "a daunting one". Knight goes on to explain that "the structure of carbohydrates is much more complex than that of proteins. Because carbohydrate structures are a branching series of linked rings, they can combine in many more ways than linear peptide chains. For comparison, consider that while three amino acids can combine in only six ways, three carbohydrate monomers can form over 1,000 different trisaccharide structures" (see page 39, first column, third and fourth full paragraphs). Location of the single N-linked glycosylation site on CD55 is not the same as knowing the structure. In view of Applicants not being able to define, nor characterize the glycostructure one of ordinary skill in the art is not clear on the variability that possibly exists within the genus of glycoproteins. For the reasons of record and the established analysis provided herein and of record there is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal

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Register at Volume 63, Number 114, pages 32639-32645 and the rejection is maintained.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 50 are vague and indefinite. In consideration of the discrepancies often encountered in the art between protein molecular weight when determined by different methods, when a molecular weight is recited to characterize a protein the claims should include not only the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel electrophoresis, gel filtration or some other method, but also whether the determination was made under denaturing or non-denaturing conditions and whether reducing or non-reducing conditions were are used.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The rejection of claims 1 and 50 under 35 U.S.C. 102(b) as being anticipated by Karnauchow et al. (Journal of Virology 70(8): 5143-5152, August 1996) is maintained.

Applicants argue, "70 or 75 kD are not within the range of about 82 kD", see page 13 of Remarks. This point of view and arguments have been carefully considered but found unpersuasive.

75 kD is regarded as being in the range of about 82 kD and the disclosed antibody is specific for the glycostructure. Accordingly, the rejection is maintained over the claims cited.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

06 March 2006